

Serial No.: 10/757,159  
Examiner: Laura C. Schell  
Group Art Unit: 3767

### STATUS OF CLAIMS

Claims 11-20, 22, 23, and 26-38 are presently pending and under examination, claims 1-10, 21, and 24-25 having been previously cancelled.

### REMARKS

In the Office Action, the Examiner has required election of a single disclosed species for prosecution on the merits and to which the claims shall be restricted if no generic claim is finally held to be allowable. The Examiner indicates that the species are independent or distinct because claims to the different species recite the mutually exclusive characteristics of such species and are not obvious variants of each other. The following are the two groups of allegedly distinct system species and injectable material species:

#### System Species

Species A: Figs. 1, 2, and 5

Species B: Fig. 3A

Species C: Fig. 3B

Species D: Fig. 3C

Species E: Fig. 3D

Species F: Fig. 3E

Species G: Figs. 6A and 6B

#### Injectable Material Species

Species 1: material comprising a cross-linked material, a carrier and matrix material

Species 2: a bioactive molecule

In response, pursuant to 35 U.S.C. § 121, Applicant elects with traverse the following species: (1) system species: Figs. 1, 2, and 5 (Species A); and (2) injectable material species: material comprising a cross-linked material, a carrier and matrix material (Species 1), for initial prosecution on the merits. Claims 11-20, 22, 23, and 26-38 encompass the elected Species A. Claims 11-20, 22, 23, 26-32, and 34-38 encompass the elected Species 1.

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The election is made with traverse for the following reasons:

It is believed that search and examination of all pending claims may be made without serious burden. The species are sufficiently limited in number and require the same or related fields of search such that prior art applicable to one species would likely be applicable to another species. Specifically, a search of prior art for the delivery system of Species A would be applicable to the delivery system of Species G and likewise, a search of prior art relating to a helical mixing member component of the delivery system of Species B would be applicable to the helical mixing members of Species C, D, E, and F.

Further, regarding the "system species" election requirement, Applicant believes that the election requirement was made in error. Specifically, the Examiner has characterized the various Species A through G as pertaining to patentably distinct "systems" that have mutually exclusive characteristics. However, whereas Species A (Figs. 1, 2, and 5) and Species G (Figs. 6A and 6B) pertain to delivery systems, Species B (Fig. 3A), Species C (Fig. 3B), Species D (Fig. 3C), Species E (Fig. 3D) and Species F (Fig. 3E) do not pertain to delivery systems. Rather, Figs. 3A-3E depict embodiments of just the mixing member element of the delivery system. Specifically, Figs. 3A-3E, which the Examiner calls Species B, C, D, E, and F, respectively, depict "one embodiment of the invention [wherein] the mixing member 10 is in the form of an elongated helical element." (col. 3, lines 51-52). Thus, rather than being delivery systems themselves, Species B, C, D, E, and F show configurations of the mixing member element that may be used with the delivery system of Species A or Species F.

Any of Species B, C, D, E, or F can be combined with either Species A or Species G, with claims directed to either Species A or Species G being the generic linking claim for Species B, C, D, E, and F. Thus, Species B, C, D, E, and F do not share mutually exclusive characteristics with respect to Species A and Species G.

In addition, Applicant notes that the Examiner has failed to include Figure 4 in Species A and G. Figure 4 depicts a driver system that is common to the delivery systems of both Species A and G. Thus, Applicant requests that the Examiner include the invention depicted in Figure 4 as part of elected Species A. Thus, the elected Species A would include Figures 1, 2, 4, and 5.

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Regarding the injectable materials species election requirement, Applicant believes that the election requirement was made in error. Specifically, the Examiner requires that the Applicant choose between an injectable material comprising Species 1 (material comprising a cross-linked material, a carrier and matrix material) and Species 2 (a bioactive molecule). Applicant disagrees with the Examiner's assertion that these different species recite mutually exclusive characteristics. Instead of being mutually exclusive, the specification and claims clearly state that the injectable material can encompass just the "material comprising a cross-linked material, a carrier and matrix material," or a combination of this material *and* a bioactive molecule. These species are not Markush group elements. Rather, as indicated in the specification, "bioactive materials may be *additionally included* with the shear-sensitive injectable material 13" (col. 5, lines 40-42; Claim 33) and are not mutually exclusive components of the claimed injectable material.

Even if, for the sake of argument, it was assumed that the bioactive molecules and the "material comprising a cross-linked material, a carrier and matrix material" are Markush group elements, according to MPEP 803.02, if the members of the Markush group are sufficiently few in number [here, there are only *two* members] or so closely related that a search and examination of the entire claim can be made without serious burden, then the Examiner must examine all the members of the Markush group in the claim on the merits, even though they are directed to independent and distinct inventions. Applicant states that examination of the claims of both Species 1 and Species 2 would not pose an undue burden on the Examiner.

Claims 11 and 18 are linking claims. Accordingly, these claims are to be considered with the elected invention. If the elected invention is found allowable, the linking claims will also be examined. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. See MPEP 809.03.

Should the Examiner be of the view that an interview would expedite consideration of the application, request is made that the Examiner telephone the Applicant's attorney at 908-518-7700 in order that any outstanding issues be resolved.

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### CONCLUSION

Applicants respectfully submit that all pending claims are in condition for allowance, early notification of which is earnestly solicited. Should the Examiner be of the view that an interview would expedite the application at large, request is made that the Examiner telephone the undersigned attorney at (908) 518-7700, ext. 7 in order to resolve any outstanding issues.

### FEEs

The Office is authorized to charge any fees required, including the fee for a two-month extension of time to deposit account number 50-1047.

Respectfully submitted,



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I hereby certify that this correspondence and any document referenced herein is being sent to the United States Patent and Trademark office via Facsimile to: 571-273-8300 on 11/12/08

Marjorie Scariati  
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(Signature)